UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

STATE OF MISSOURI, *et al.*,
Intervenor-Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION, *et al.*,
Defendants,

and

DANCO LABORATORIES, LLC,
Intervenor-Defendant.

Case No. 2:22-cv-00223-Z

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF GENBIOPRO, INC.'S MOTION FOR LEAVE TO INTERVENE

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GenBioPro, Inc. ("GenBioPro") respectfully submits this Memorandum of Points and Authorities in Support of GenBioPro's Motion for Leave to Intervene pursuant to Rules 24(a) and 24(b) of the Federal Rules of Civil Procedure.

PRELIMINARY STATEMENT

GenBioPro seeks to intervene in this case to protect the availability of generic mifepristone, a product that is foundational to its business and critical to the healthcare of countless Americans. GenBioPro has held a U.S. Food and Drug Administration ("FDA")-approved Abbreviated New Drug Application ("ANDA") to market generic mifepristone since 2019. GenBioPro is the sole supplier of generic mifepristone in the United States, and sales of mifepristone, along with the associated drug misoprostol, represent the majority of the company's revenue.

In their Amended Complaint, ECF No. 217, Intervenor-Plaintiffs (the "States") seek an order rescinding FDA's 2019 approval of GenBioPro's generic mifepristone as safe and effective for its intended use. The States also ask the Court to vacate other regulatory actions that impact the conditions under which mifepristone can be prescribed and distributed to patients, threatening serious harm to GenBioPro and the many Americans it serves.

GenBioPro joins in the Rule 12(b) objections by both the Federal Defendants and Intervenor-Defendant Danco, which foreclose reaching any merits issues in this case. By seeking to intervene, GenBioPro expressly does not in any way waive such objections or acquiesce in venue in this District. Rather, GenBioPro seeks intervention to ensure that its rights are fully and adequately represented in the event this case proceeds any further in this Court. GenBioPro is seeking to intervene now, at the pleading stage, to ensure the timing of its motion causes no prejudice to the existing parties.

GenBioPro seeks to exercise its right under Rule 24 to appear and be heard against challenges attacking its product's approval, just as Danco was previously permitted to intervene

to defend its product. *See, e.g.*, *Apotex Inc. v. FDA*, 508 F. Supp. 2d 78, 80 n.2 (D.D.C. 2007) (drug manufacturer permitted to intervene as of right "because the plaintiff [sought] to set aside the FDA's decision as to its approval status"); *Eagle Pharms., Inc. v. Price*, 322 F.R.D. 48, 49–50 (D.D.C. 2017) (manufacturer with FDA approval for generic drug product permitted to intervene because plaintiff's requested relief would prevent intervenor "from marketing its generic product"); *see also One Beacon Ins. Co. v. T. Wade Welch & Assocs.*, No. H-11-3061, 2012 WL 1231750, at *2 (S.D. Tex. Apr. 12, 2012) ("With respect to a potential intervenor seeking to *defend* an interest being attacked by a plaintiff in a lawsuit, . . . the intervenor is a real party in interest when the suit was intended to have a 'direct impact' on the intervenor." (quoting *Ross v. Marshall*, 426 F.3d 745, 757 n.46 (5th Cir. 2005))). At minimum, this Court should grant permissive intervention under Rule 24(b).

BACKGROUND

In April 2019, FDA approved GenBioPro's ANDA for Mifepristone Tablets, 200mg ("generic mifepristone"), a generic version of the medication mifepristone. Mifepristone, which is FDA-approved as safe and effective for performing medical abortions, has been marketed and prescribed under the brand name Mifeprex for almost a quarter of a century, since 2000. Mifepristone's approval is subject to a set of distribution and administration conditions known as a "Risk Evaluation and Mitigation Strategy" or "REMS," which FDA has periodically revised and updated, including a revision in 2016. *See* 2016 Supplement Approval (Mar. 29, 2016), ECF No. 217-2 at 000512–19. When FDA approved GenBioPro's generic mifepristone ANDA, FDA subjected generic mifepristone to a single, shared REMS with Mifeprex. *See* 2019 FDA ANDA Approval Letter to GenBioPro (Apr. 11, 2019), ECF No. 217-3 at 000632–38.

In April 2021, during the COVID-19 public health emergency, FDA determined that requiring a patient to visit a clinic to receive mifepristone, as the then-current REMS directed,

could pose serious risks to those patients and healthcare personnel. FDA stated that it intended to exercise enforcement discretion with respect to the in-person dispensing requirement. *See* FDA Letter to ACOG (Apr. 12, 2021), ECF No. 217-3 at 000644–45. In December 2021, FDA stated that it intended to make changes to the mifepristone REMS which included modification of the in-person dispensing requirement. *See* FDA Letter to AAPLOG (Dec. 16, 2021), ECF No. 217-3 at 000654. On January 3, 2023, FDA published a new, shared REMS for Mifeprex and generic mifepristone ("2023 REMS"). The 2023 REMS no longer limits mifepristone dispensing to certain healthcare settings, allowing patients to receive mifepristone by mail or from a certified pharmacy. REMS Single Shared System for Mifepristone (Jan. 2023), ECF No. 217-3 at 000782–87.

In November 2022, the Alliance for Hippocratic Medicine and other private plaintiffs not including the present Intervenor-Plaintiff States (the "Alliance Plaintiffs") filed this action against FDA and various federal officials (the "Federal Defendants"). The Alliance Plaintiffs sought to declare unlawful all regulatory approvals of mifepristone, including FDA's 2000 Mifeprex approval, its subsequent REMS modifications, and its approval of GenBioPro's 2019 ANDA for generic mifepristone. The Alliance Plaintiffs alleged no independent basis to vacate GenBioPro's 2019 ANDA; rather, their sole basis for seeking to vacate the 2019 ANDA was that the ANDA approval depended on the allegedly unlawful 2000 approval of Mifeprex. *See* Alliance Compl. ¶¶ 383–89, ECF No. 1.

On April 7, 2023, this Court entered an order staying FDA's 2000 approval of Mifeprex. *All. for Hippocratic Med. v. FDA*, 668 F. Supp. 3d 507, 560 (N.D. Tex. 2023). That order and further substantive proceedings in this case were stayed for more than a year and a half while Defendants sought appellate review. ECF No. 144; *Danco Lab'ys, LLC v. All. for Hippocratic Med.*, 143 S. Ct. 1075 (2023). In June 2024, the Supreme Court concluded that the Alliance

Plaintiffs lacked standing. *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 396 (2024). On remand, the Alliance Plaintiffs voluntarily dismissed their claims. ECF No. 203.

During the pendency of this case, the Court has granted two motions to intervene. *First*, the Court allowed Intervenor-Defendant Danco Laboratories, LLC ("Danco"), the manufacturer of Mifeprex, to intervene under Rule 24(b). *See* ECF No. 33 at 3. *Second*, in January 2024, while the case was pending before the Supreme Court and proceedings in this Court were otherwise stayed (and more than a year after the case began), the Court allowed the States of Missouri, Kansas, and Idaho to intervene based on their allegations of new harms to their sovereign interests implicated by the regulatory actions at issue in the Alliance Plaintiffs' complaint. ECF No. 175. Like the Alliance Plaintiffs' complaint, the States' original complaint challenged GenBioPro's 2019 ANDA approval only to the extent that it was premised on the allegedly unlawful 2000 approval of Mifeprex. *See* States' Compl. ¶¶ 406–15, ECF No. 176.

After the Supreme Court's decision that the Alliance Plaintiffs lacked standing, the States moved for leave to file an amended complaint, ECF Nos. 195, 195-1, and this Court granted leave to amend on January 16, 2025, ECF No. 215. The Amended Complaint, for the first time in this case, challenges GenBioPro's ANDA approval on grounds other than the ANDA's dependence on FDA's 2000 Mifeprex approval. Am. Compl. ¶¶ 763–67, 784–88, ECF No. 217 (challenging 2019 ANDA specifically in two of the Amended Complaint's five counts). The Amended Complaint also contains significant new allegations regarding GenBioPro and the 2019 ANDA, including allegations about the distribution and utilization of GenBioPro's product by pharmacies, patients, and other organizations, and harms allegedly inflicted on the States specifically because of FDA's generic mifepristone approval. *See* Am. Compl. ¶¶ 9, 19–20, 164–65, 259, 293–95, 302, 389, 434,

753–55, 788; *see also id.* ¶ 756 ("[T]he 2019 generic approval aggravates and worsens Plaintiff States' harms.").

The Federal Defendants and Danco then filed renewed motions to dismiss, arguing that (1) venue is improper in the Northern District of Texas; (2) the suit is jurisdictionally invalid; (3) the States' claims are barred by a failure to exhaust mandatory administrative remedies; and (4) the statute of limitations bars the States' claims regarding 2016 changes to the REMS. *See* ECF Nos. 218–19; ECF Nos. 221–22.

Neither the Federal Defendants nor Danco have answered the States' Amended Complaint (or any other complaint in this action), nor has the administrative record been produced for any FDA decision challenged in the States' Amended Complaint.

ARGUMENT

I. GenBioPro Is Entitled to Intervene As of Right Under Federal Rule 24(a)

Federal Rule of Civil Procedure 24(a) governs intervention in a proceeding as a matter of right. Fed. R. Civ. P. 24(a)(2); *see Guenther v. BP Retirement Accumulation Plan*, 50 F.4th 536, 542 (5th Cir. 2022). Rule 24(a) is framed in mandatory terms that favor intervention. Fed. R. Civ. P. 24(a). Specifically, under Rule 24(a)(2), "the court *must* permit *anyone* to intervene," *id.* (emphases added), whose request satisfies the following criteria:

> (1) the application for intervention must be timely; (2) the applicant must have an interest relating to the property or transaction which is the subject of the action; (3) the applicant must be so situated that the disposition of the action may, as a practical matter, impair or impede his ability to protect that interest; [and] (4) the applicant's interest must be inadequately represented by the existing parties to the suit.

Guenther, 50 F.4th at 542 (quoting *Texas v. United States*, 805 F.3d 653, 657 (5th Cir. 2015)).

The Fifth Circuit has made clear that "court[s] should 'liberally construe[]' the test for mandatory intervention" and should "'allow intervention where no one would be hurt and the greater justice could be attained.'" *Rotstain v. Mendez*, 986 F.3d 931, 937 (5th Cir. 2021) (quoting

Texas, 805 F.3d at 656–57). Accordingly, "the inquiry under subsection (a)(2) [of Rule 24] is a flexible one, which focuses on the particular facts and circumstances surrounding each application." *Edwards v. City of Houston*, 78 F.3d 983, 999 (5th Cir. 1996) (en banc) (quoting *United States v. Tex. E. Transmission Corp.*, 923 F.2d 410, 413 (5th Cir. 1991)). Applying these principles, GenBioPro is entitled to intervene in this case as of right.

A. GenBioPro's Motion to Intervene Is Timely

GenBioPro's request to intervene in this action is timely. The Fifth Circuit assesses timeliness by considering four factors: "(1) the length of time during which the intervenor actually knew or reasonably should have known of his interest in the case; (2) the extent of prejudice to the existing parties to the litigation; (3) the extent of prejudice to the would-be intervenor; and (4) unusual circumstances." *Adam Joseph Res. v. CNA Metals Ltd.*, 919 F.3d 856, 865 (5th Cir. 2019) (citing *Stallworth v. Monsanto Co.*, 558 F.2d 257, 264–66 (5th Cir. 1977)). Although the factors are not a rigid formula—"[a] motion to intervene may still be timely even if all the factors do not weigh in favor of a finding of timeliness," *John Doe No. 1. v. Glickman*, 256 F.3d 371, 376 (5th Cir. 2001)—they all point in favor of GenBioPro's timely intervention here.

First, GenBioPro has promptly sought to intervene upon becoming "aware that its interests would no longer be protected by the original" Defendants. *Sierra Club v. Espy*, 18 F.3d 1202, 1206 (5th Cir. 1994).

GenBioPro had good reason to "legitimately believe[]" that its interests were protected by the existing Defendants at prior stages of the litigation. *Espy*, 18 F.3d at 1206. Indeed, the Alliance Plaintiffs' complaint was a broad challenge to mifepristone approval as a whole. Its attack on GenBioPro's 2019 ANDA approval turned exclusively on the alleged illegality of FDA's 2000 approval of Danco's New Drug Application ("NDA") for Mifeprex, on which the Alliance Plaintiffs asserted FDA unlawfully relied "as a means to approve GenBioPro's generic drug."

Alliance Compl. ¶ 384, ECF No. 1. At that stage of the case, GenBioPro's interests were represented because the Federal Defendants' and Danco's defenses of the 2000 NDA approval necessarily responded in full to the Alliance Plaintiffs' challenge to GenBioPro's 2019 ANDA approval. *See All. for Hippocratic Med. v. FDA*, 78 F.4th 210, 241 (5th Cir. 2024) (noting that the Alliance Plaintiffs "did not introduce evidence showing that they are likely to be injured by the 2019 Generic Approval" instead "point[ing] to the 2000 Approval, arguing that the two actions impose the same injuries"), *rev'd sub nom. FDA v. All. for Hippocratic Med.*, 602 U.S. 367 (2024).

Since then, the nature of the threat to GenBioPro's interests has "changed dramatically." *Espy*, 18 F.3d at 1206. The Alliance Plaintiffs have voluntarily dismissed their complaint, and the States have filed an Amended Complaint that challenges the legality of GenBioPro's 2019 ANDA approval directly on new, *freestanding* grounds that are independent of Danco's 2000 NDA approval for Mifeprex (which the States no longer challenge). In particular, the Second Claim of the Amended Complaint now alleges that the 2019 ANDA approval was ultra vires and arbitrary and capricious under the Administrative Procedure Act ("APA") in its own right. Am. Compl. ¶¶ 763–67. That argument is independent from Danco's ability to market mifepristone, and GenBioPro is the only manufacturer with an interest in defending it. Likewise, the Fifth Claim of the Amended Complaint alleges that GenBioPro's 2019 ANDA approval was improperly premised on FDA's allegedly unlawful 2016 REMS modifications. *Id.* ¶ 785 ("Because the FDA relied on the unlawful 2016 Major Changes labeling as a means to approve GenBioPro's generic drug, Mifepristone Tablets, 200 mg, the 2019 ANDA Approval was unlawfully approved."); *see id.* ¶¶ 784, 786–88.

Notably, Danco lacks any commercial incentive to oppose the States' new challenges to GenBioPro's 2019 ANDA approval. If the States succeed in their claim that the 2016 REMS

modifications were invalid, the implications may be different for Danco and GenBioPro because GenBioPro did not sell mifepristone under the 2016 labeling regime, while Danco did. *Id.* ¶ 788. GenBioPro thus cannot rely on Danco—its economic competitor—to fully represent its interests with respect to this challenge. *See* section I.D, *infra* (further explaining why GenBioPro's interests are not adequately represented by Danco in this case).

In addition to the States' new legal theories targeting GenBioPro's ANDA approval, the Amended Complaint also contains numerous new allegations expressly and specifically targeting GenBioPro and its product that were not part of the Alliance Plaintiffs' complaint or the States' original complaint. *See* Am. Compl. ¶¶ 9, 19–20, 164–65, 259, 293–95, 302, 316, 389, 434, 753–56, 788. In fact, the Amended Complaint discusses GenBioPro more than 25 times, while the States' original Complaint and the Alliance Plaintiffs' complaint barely mentioned GenBioPro's existence. Just as the States' intervention motion identified events that had altered their interests in the year since the case was filed, *see* ECF No. 152 at 9, GenBioPro has only recently "be[come] aware that its interests would no longer be protected by the original parties." *Espy*, 18 F.3d at 1206.

Second, there is no "prejudice to the existing parties to the litigation." *Adam Joseph Res.*, 919 F.3d at 865. Notwithstanding extensive litigation of preliminary justiciability issues that has occurred so far in this Court and the appellate courts, this case is now starting afresh, with a new operative pleading, and without any of the original plaintiffs. No party has filed a responsive pleading, and the administrative record has not been produced. This is thus effectively a brand new lawsuit, without any substantive litigation regarding the allegations in the Amended Complaint.

In response to the Amended Complaint, GenBioPro's proposed Rule 12 substantive submission (attached hereto) merely adopts the arguments in Danco's and the Federal Defendants' existing motions to dismiss. GenBioPro's proposed filing injects no new arguments into the current litigation, and it therefore requires no separate response—or any additional work—from the existing parties at this stage.[1] GenBioPro notified the parties of its intent to intervene, including the non-additive nature of its proposed Rule 12 substantive submission, before the States' opposition to the pending motions to dismiss was due, as the States' opposition reflects. *See* ECF No. 228 at 13 (referencing GenBioPro's upcoming intervention motion). Accordingly, even if, *arguendo*, GenBioPro previously "knew or reasonably should have known about [its] interest in the action" (it did not), there is no "prejudice which would result from the would-be intervenor's failure to request intervention" at such earlier time. *Stallworth*, 558 F.2d at 265. To the extent the parties may need to take additional future actions in the litigation as a result of GenBioPro's intervention, that effect would be "inherent to intervention generally, and not specific to delay." *Rotstain*, 986 F.3d at 939. Any extra effort the existing parties will need to expend as a result of GenBioPro's participation therefore "is not relevant to the timeliness inquiry." *See id.*

Nor would GenBioPro's intervention delay resolution of the case. This consideration typically weighs against proposed intervenors only when they seek to participate after entry of judgment. *See Edwards*, 78 F.3d at 1001 ("[M]ost of our case law rejecting petitions for intervention as untimely concern motions filed after judgment was entered in the litigation."). Again, this case is still in its early stages, as the Federal Defendants have not yet produced an

[1] If this case survives the pending Rule 12 motions, GenBioPro anticipates raising arguments of its own on the merits at later stages of the litigation. Any impact on the States from having to address those merits arguments would not qualify as cognizable prejudice, however, because it is "inherent to intervention generally" rather than linked to the timing of intervention. *See Rotstain*, 986 F.3d at 939.

administrative record for any of the FDA actions challenged in the Amended Complaint and no briefing on the merits has occurred.

Third, GenBioPro would be significantly prejudiced by an inability to participate in this case. The States seek a nationwide injunction to "rescind" the federal approval of generic mifepristone, ECF No. 217 at 197, which, along with the associated drug misoprostol, comprises the majority of GenBioPro's business. As a nonparty, GenBioPro would not "be able to participate" in the litigation, nor "be able to appeal" an adverse ruling, *Glickman*, 256 F.3d at 379, that harms its interests, *see Espy*, 18 F.3d at 1206–07. Because of the "direct impact" that "the suit [i]s intended to have" on GenBioPro's ability to market its product, precluding GenBioPro from participating to defend its interests would be profoundly prejudicial. *Ross*, 426 F.3d at 757 n.46 (quoting *Sierra Club v. Glickman*, 82 F.3d 106, 109 (5th Cir. 1996)). Nor are there any "unusual circumstances" counseling against permitting GenBioPro to participate. *Adam Joseph Res.*, 919 F.3d at 865. The governing factors each point in favor of timeliness.

B. GenBioPro Has Direct Interests Relating To the Action

GenBioPro has multiple interests in this action that are "direct, substantial, and legally protectable." *Glickman*, 256 F.3d at 379 (cleaned up) (citing *Espy*, 18 F.3d at 1207).

GenBioPro has a direct interest as "the intended beneficiar[y] of the challenged federal policy," namely FDA's 2019 ANDA approval, *Texas*, 805 F.3d at 660, and a "legally protectable interest in the regulatory scheme," *Wal-Mart Stores, Inc. v. Tex. Alcoholic Beverage Comm'n*, 834 F.3d 562, 566 (5th Cir. 2016). Because the States' Amended Complaint seeks to vacate the 2019 ANDA approval and other agency actions governing the marketing, sale, and distribution of GenBioPro's product, whether GenBioPro "will or will not be" able to market generic mifepristone under its current label in the United States "depend[s] on the outcome of this case." *Texas*, 805

F.3d at 660. GenBioPro thus has a direct stake in the outcome of the litigation that is "sufficiently concrete and specific to support" intervention. *Id.* at 660–61.

It is also "obvious that the economic interests of [GenBioPro] are at stake" in this lawsuit. *See Espy*, 18 F.3d at 1207. "[E]conomic interests can justify intervention when they are directly related to the litigation." *Wal-Mart*, 834 F.3d at 568. GenBioPro is the sole supplier of generic mifepristone in the United States, and sales of mifepristone, along with the associated drug misoprostol, are the company's majority source of revenue. The States seek to void the 2019 ANDA approval that allows GenBioPro to market generic mifepristone, as well as FDA actions on the REMS regarding mifepristone distribution. The States' requested relief thus "threatens a 'prospective interference'" with GenBioPro's ability to market its product in the United States, presenting a direct, concrete, and particularized threat to GenBioPro's economic interests that justifies intervention. *Brumfield v. Dodd*, 749 F.3d 339, 343 (5th Cir. 2014) (quoting *Black Fire Fighters Ass'n of Dallas v. City of Dallas*, 19 F.3d 992, 994 (5th Cir. 1994)); *see Wal-Mart*, 843 F.3d at 568 (collecting cases "permitting intervention based on economic interests").

C. Disposition of This Action May Impair GenBioPro's Ability to Protect Its Interests

If the States' claims succeed and the challenged FDA decisions on mifepristone are vacated, GenBioPro may be hindered in marketing its primary product and face severe financial and operational distress. These risks amply satisfy the third Rule 24(a) factor, which requires only a "*possibility* that [a party's] interest *could* be impaired or impeded" absent intervention. *La Union del Pueblo Entero v. Abbott*, 29 F.4th 299, 307 (5th Cir. 2022) (emphases added).

D. GenBioPro's Interests Are Not Adequately Represented By Existing Parties

Neither the Federal Defendants nor Danco adequately represent GenBioPro's interests at this stage of the case. The burden of demonstrating inadequate representation "is 'minimal'":

"The applicant need only show that representation 'may be' inadequate." *Espy*, 18 F.3d at 1207 (quoting *Trbovich v. United Mine Workers*, 404 U.S. 528, 538 n.10 (1972)).

While representation may be presumed adequate when "one party is a representative of the absentee by law" or the "would-be intervenor has the same ultimate objective as a party to the lawsuit," *Brumfield*, 749 F.3d at 345 (quoting *Edwards*, 78 F.3d at 1005), neither of those situations is present here. None of the existing Defendants is GenBioPro's "legal representative." *Id.* at 345. Quite the contrary—FDA is GenBioPro's *regulator*, and Danco is GenBioPro's *competitor*.

Neither Danco nor the Federal Defendants have "the same ultimate objective as" GenBioPro. *Id.* (quoting *Edwards*, 78 F.3d at 1005). Danco's stated "objective is to maintain *its* regulatory approval and ability to continue providing *Mifeprex* that can be dispensed to patients." Mem. of P. & A. in Supp. of Danco's Unopposed Mot. for Leave to Intervene at 7, ECF No. 20 (emphases added). Danco is GenBioPro's direct competitor, and its interest does not necessarily extend to protecting GenBioPro's 2019 regulatory approval for *generic* mifepristone. *See Edwards*, 78 F.3d at 1005–06 (rejecting the presumption of adequate representation when intervenors and existing parties are "competitors"). GenBioPro should not be forced to rely on Danco to represent GenBioPro's interests under these circumstances.

Danco's interests and GenBioPro's interests were initially aligned when the Alliance Plaintiffs challenged GenBioPro's ANDA approval based only on its reliance on Danco's NDA approval. *See supra* § I.A (citing Alliance Compl. ¶ 384). At that point, Danco's efforts to protect its regulatory approval of Mifeprex necessarily aligned with GenBioPro's interests. But the States' Amended Complaint offers a different challenge, separately targeting GenBioPro's 2019 ANDA approval on grounds unrelated to the 2000 Mifeprex approval. Am. Compl. ¶¶ 763–67, 783–88.

Indeed, the Amended Complaint does not challenge the 2000 Mifeprex approval at all. Thus, Danco's interest in this action now—to protect post-2000 regulatory decisions addressing distribution of Mifeprex—does not necessarily extend to protecting the approval of generic mifepristone produced by its competitor. *See Brumfield*, 749 F.3d at 345 (finding inadequate representation when two parties' interests did not "align precisely"); *see also Texas*, 805 F.3d at 662 (noting that adversity of interest existed when parties had "the same objective," but their "interests diverged . . . in certain key respects").

Further, courts routinely recognize that "[g]overnment agencies . . . must represent the public interest, not just the economic interests of one" manufacturer. *Heaton v. Monogram Credit Card Bank of Ga.*, 297 F.3d 416, 425 (5th Cir. 2002). FDA also has objectives in protecting the independence and flexibility of the regulatory process that are broader than GenBioPro's unique interest in protecting the regulatory approval of its product. *See Wal-Mart*, 834 F.3d at 569 (finding inadequacy of representation where intervenor argued, *inter alia*, "that its interests—protecting its members' businesses—[were] narrower than the Commission's broad public mission."). GenBioPro's objective, in contrast, is to ensure that its generic mifepristone is available to the prescribers and patients that need it.

Finally, the fact that GenBioPro's interests and the Federal Defendants' interests "may diverge in the future," even if they did currently "appear to share common ground, is enough to meet [the intervenor's] burden on this issue." *Heaton*, 297 F.3d at 425. GenBioPro accordingly meets all of Rule 24(a)'s requirements to intervene as of right. The Court should grant GenBioPro's motion.

II. In The Alternative, the Court Should Permit GenBioPro to Intervene Under Rule 24(b)

If the Court finds that GenBioPro does not have a right to intervene under Rule 24(a), the Court in its discretion should permit GenBioPro to intervene under Rule 24(b). Courts may allow intervention on a permissive basis where the movant "has a claim or defense that shares with the main action a common question of law or fact." Fed. R. Civ. P. 24(b)(1)(B). In considering a motion for permissive intervention, courts ask whether the motion is timely and whether the proposed intervention will "unduly delay or prejudice the adjudication of the original parties' rights." Fed. R. Civ. P. 24(b)(3); *see, e.g.*, *Newby v. Enron Corp.*, 443 F.3d 416, 424 (5th Cir. 2006).

GenBioPro's interest in maintaining the availability of generic mifepristone implicates common questions of both law and fact at issue in this case. Although "[t]imeliness under mandatory intervention is evaluated more leniently than under permissive intervention," *Rotstain*, 986 F.3d at 942, GenBioPro's motion is timely under either standard. GenBioPro moves to intervene promptly after learning that its interests are no longer adequately represented in this case, and the motion is timely for the reasons outlined above. GenBioPro's intervention will not delay the litigation or prejudice the rights of either the States, the Federal Defendants, or Danco. GenBioPro should be permitted to intervene under Rule 24(b).

CONCLUSION

For the foregoing reasons, the Court should grant GenBioPro's Motion for Leave to Intervene.

Dated: February 25, 2025

Respectfully submitted,

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** Pro hac vice forthcoming*

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CERTIFICATE OF SERVICE

I certify that on February 25, 2025, I electronically filed the foregoing Memorandum of Points and Authorities using the CM/ECF system. Notice of this filing will be sent by operation of the Court's electronic filing system to all parties of record.

/s/ Christopher M. Odell
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